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**Re: Request for Information: Building a 21st Century Bioeconomy
[Federal Register/Vol. 76, No. 196]**

December 6, 2011

Thank you for the opportunity for *FasterCures* to comment on the National Bioeconomy Blueprint. We applaud the Administration's efforts to harness research innovations in the life sciences to address national challenges. We also agree that bolstering biomedical innovation stands to advance our nation's economic growth and competitiveness.

Within the life sciences there are many imperatives, but our response focuses on one core objective – speeding up the time it takes to get new therapies for deadly and debilitating diseases from discovery to patients.

Despite the human and financial capital flowing through our healthcare system, the fact remains that more than 100 million Americans suffer from cancer, Alzheimer's disease, diabetes, Parkinson's disease, heart disease, and others for which there are still no cures, and, in many cases, few meaningful treatment options. Be it lack of medical breakthroughs, limited resources, or restrictive policies that are stalling progress, patients are paying the price in prolonged suffering or in life or death consequences.

Over the past few decades, the United States has refined a productive framework for developing biomedical innovations and therapies and bringing them to market, but we are now at risk of losing our competitive edge. The statistics are familiar: for every 10,000 compounds discovered, only one gets approvedⁱ, and it usually takes 14 years and upwards of \$1.2 billion to reach the marketⁱⁱ. Roadblocks abound, including a dearth of funding and support for translational and early-stage clinical research, a lack of information- and data-sharing among the stakeholders, and misaligned incentives among the stakeholders. **However, we believe the tough times facing the biomedical industry are beginning to stimulate and necessitate greater collaboration, as well as an exploration of ways to share capabilities in pre-competitive areas.**

Ensuring that the right resources and tools are in place to move basic discoveries in the lab through the therapeutic pipeline is not just about saving money and creating high-skill, high-wage jobs – though it will do both. (In fact, according to a recently released Milken Institute report,

[The Global Biomedical Research Industry: Preserving U.S. Leadership](#), the biomedical sector directly and indirectly accounts for some 5 million U.S. jobs in pharma, biotech, medical devices, research and testing.) At its core, it is about saving *lives* by saving time.

The RFI poses many provocative and important questions, but for our response, we focus on the following four:

Question #1: Identifying one or more grand challenges for the bioeconomy, and suggesting steps that would need to be taken to achieve it/them.

Question #2: Identifying federal funding priorities in research, technologies, and infrastructures that provide the foundation for the bioeconomy.

Question #16: Recommending high-impact opportunities for public-private partnerships related to the bioeconomy – including possible goals and partners.

Question #17: Recommending high impact opportunities for pre-competitive collaboration in the life sciences – including the role government should play in developing them.

Regardless what actions are taken to move the bioeconomy blueprint forward, we strongly encourage looking for opportunities to support cross-sector, cross-disciplinary collaboration within those initiatives. This emerging research paradigm is proving instrumental in speeding up the time it takes to turn discoveries into treatments and cures.

Additionally, we recommend incorporating patient and venture philanthropy groups and perspectives in developing and implementing the blueprint as much as possible. With an extensive understanding of the needs of their particular community and disease, they are a critical part of any agenda-setting process.

<p><u>Question #1</u>: Identifying one or more grand challenges for the bioeconomy, and suggesting steps that would need to be taken to achieve it/them.</p>

There are literally thousands of different directions in which we could take this question – challenges that address unmet medical needs; high-cost, high-casualty diseases; more efficient and effective clinical trial models; etc. – but instead we’d like to focus on an issue the federal government has already put a tremendous amount of time and effort into incentivizing: the better collection and use of patient data. We believe there is an opportunity to optimize this investment to advance medical science and speed the path to cures.

From its inception, *FasterCures* has advocated for more widespread, collaborative, and effective use of patient data – particularly data derived from biospecimens and clinical encounters contained in electronic health records – for research. We have produced multiple reports on this topic, including [Think Research](#) in 2005, which urged health systems to consider research needs when developing or implementing EHR systems, and [Still Thinking Research: Strategies to Advance the Use of Electronic Health Records to Bridge Patient Care and Research](#) in 2011, which found that while much progress had been made in pushing greater adoption of EHRs in clinical care, the health IT infrastructure is still falling far short of its potential to increase understanding of disease progression and advance biomedical innovation.

One of the barriers standing in the way of research being integrated into an EHR system is the need for high-quality data that are annotated with patient outcomes and can be used for clinical, not just quality and outcomes, research purposes. We cite in [Still Thinking Research](#) a number of organizations that are already testing innovative models that link research and care through imaging records, biospecimens, and genomic databases with patients' electronic health records;

some examples include the Gene Partnership Project at Children's Hospital Boston; Kaiser Permanente's Research Program on Genes, Environment, and Health; and the Genetic Alliance's Biobank.

While *FasterCures* is agnostic about the disease focus of any Administration Grand Challenge, we encourage you to prioritize initiatives that address the challenges of linking large datasets and biospecimens in an intelligent way that addresses privacy concerns and advances medical discovery. While there are good models out there, they need to be scaled and replicated to reach their full potential. This would bring benefits to all researchers in all therapeutic areas, and it is an area in which the federal government can play a unique role.

In [*Still Thinking Research*](#), we recommended that the federal government develop an initiative with pilot projects that would create medical research IT modules that could be attached (plug and play) or retrofitted to existing health data systems that were built without the capacity to accommodate research.

To ensure this initiative reaches its full potential, the federal government should consider the need to harmonize standards for collecting genomic and molecular data and integrate these into an EHR. Genetic testing is rapidly becoming part of routine medical care, and this will keep expanding. But despite the fact that nine of the top ten causes of death in the U.S. have genetic components, there is no uniform and systematic effort to build capacity for incorporating genomic and molecular data in the national electronic health IT infrastructure.

H. Steven Wiley, a biologist at the Pacific Northwest National Laboratory talked about the data deluge in a December 1 [New York Times article](#) saying "We have these giant piles of data and no way to connect them." In the same article, Isaac Ro, an analyst at Goldman Sachs noted that he believes the field of bioinformatics for genetic analysis will be one of the biggest areas of disruptive innovation in life science tools over the next few years.

Question #2: Identifying federal funding priorities in research, technologies, and infrastructures that provide the foundation for the bioeconomy.

Translational Research at the National Institutes of Health (NIH)

In recent years the NIH has acknowledged the need to enhance its commitment to translational research so that Americans will see a better return on the enormous investment of their tax dollars in the form of improved health and cures for disease. The NIH Roadmap, launched in September 2004, set many of the right goals:

- fostering more collaborative research,
- linking existing clinical research networks,
- providing core services to aid those conducting translational research, and
- supporting training and career development of physician-investigators.

At the heart of this effort is the newly proposed **National Center for Advancing Translational Sciences (NCATS)**, created by Director Francis Collins to bring together under one roof many of the translational research activities that already exist at NIH, such as:

- the National Chemical Genomics Center;
- the Therapeutics for Rare and Neglected Diseases (TRND) program;
- the Rapid Access to Interventional Development (RAID) program;
- the Clinical and Translational Science Awards (CTSA) program; and
- the NIH-FDA Joint Leadership Council.

By serving as a central point of access to resources, tools and expertise related to translational medicine; NCATS will foster efficiencies in the system from which patients can benefit. For example, given its status as a neutral third party, NCATS may be able to serve as an honest broker to match compounds abandoned by industry before approval with potential new applications, facilitate the repurposing of FDA-approved drugs, and cut across institutional boundaries to address fundamental scientific and biomedical challenges regardless of disease type.

While the NIH has historically focused on unlocking the underlying questions of biology -- that is, basic research -- Dr. Collins calls NCATS “a disruptive innovation, in a good way,” saying the motivation for the new Center is “the need to view the drug development pipeline as a scientific problem, ripe for experimentation and process engineering.”

As we note in our report [*Crossing Over the Valley of Death*](#), which catalogues the challenges in translational research and highlights effective efforts in this phase in the therapeutic development process, translating a basic discovery into a chemical or biological compound that is ready to be tested in humans is no simple matter. There are a number of complicated steps in between and the academic scientists who make the discoveries are not always equipped, or even interested, in translating them to the next step. **Up to 90 percent of research projects fail before they ever get tested in humans, and by industry’s estimates the number may be even higher— for every 5,000 compounds tested, only 5 make it to clinical trials, and only 1 eventually receives FDA approval.**ⁱⁱⁱ

Facing these steep odds of success, pharmaceutical companies, which typically fund later-stage clinical research, have become increasingly risk-averse and less likely to pursue truly innovative new products. Venture investors are seeking to support products in the later stages of clinical development – “more mature, de-risked investments,” according to a 2010 Ernst & Young report. There are increasingly fewer sources of capital for the higher-risk, earlier stages of R&D, allowing many promising ideas to fall into the “Valley of Death.”

We need to bridge the void between basic discoveries and better medicine, and the steps in between – like target validation, assay qualification, product refinement, and pre-clinical development – are necessary investments to move promising new interventions to the patient.

NCATS will provide a significant stimulus to moving ideas out of the lab and into the clinic and we fully support NIH’s willingness to disrupt its own paradigm in search of better solutions. Resourcing this new center should be a federal funding priority.

Regulatory Science at the U.S. Food and Drug Administration (FDA)

Another example of a foundation for the United States bioeconomy is the Food and Drug Administration, which regulates products that represent a quarter of all consumer spending, and industries that directly employ about four million Americans. No other agency touches American lives daily in the same way, and yet, despite such enormous responsibilities, we invest in it only two cents per day per American.

Without a well-resourced and well-equipped FDA, life-altering discoveries in the lab will not make it to the patients who need them. Increased funding for FDA must be a priority, not only to ensure that the agency can continue to review new drug applications and devices, but also to support efforts to improve its capacity for **regulatory science**. This is the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products.

In August 2011, FDA released its strategic plan for regulatory science, which provided details on its priorities, including:

- stimulating personalized medicine programs;
- developing medical countermeasures to protect against threats to global security; and
- ensuring the agency's capability to evaluate new, innovative technologies.

Building stronger ties between NIH and FDA is an important part of this effort, as NIH often has the resources (financial and scientific) to support the kind of process science FDA needs.

Though recent progress reports have been encouraging – the agency cleared 35 first-of-a-kind prescription drugs in the last 12 months, the second-highest annual number in the past decade – without additional capacity, FDA will simply not be able to keep up with the innovation coming out of the medical research community and help bring it to the marketplace to benefit patients.

An FDA that's functioning at peak performance can spur economic growth and accelerate the process of bringing to market promising breakthroughs that can help improve the quality of life, and even save lives. Ensuring support and resources for regulatory science initiatives at FDA, and building stronger links to NIH for this purpose, should be a federal priority.

Supporting Industry Innovation

Governments and businesses around the world are taking steps to gain an edge in the life sciences through tax-based incentives, recognizing the important role of innovation in driving economic growth, and the United States must keep pace in order to remain competitive in a global market.

Research and development activities in the biomedical industry carry substantial risks of product failure and investment losses. Tax incentives can mitigate these risks and encourage innovators and investors to commit time and resources to the cause. **The United States should make its R&D investment tax credit permanent and increase it by 25 percent in addition to exploring other incentive proposals and approaches that promote greater domestic R&D investment.**

The United States can also extend and enhance its global competitive position by supporting cutting-edge areas like nanotechnology, personalized medicine, stem cell research, and regenerative medicine, all of which hold immense potential. The federal government can establish a strong and sustainable foothold in these novel technologies through:

- Targeting federal funding in these areas;
- Market creation initiatives to spur discovery and commercialization; and
- Supporting adaptive trial designs, the use of surrogate endpoints, and ensuring adequate scientific expertise at FDA and NIH.

Training the Translators

Our success in any endeavor depends on having the right people with the right skills and incentives to do the work, and nowhere is the need for developing a new "breed of scientist" more evident than in the area of translational research. Many of the obstacles to translational research can be traced to the barriers that exist between basic and clinical scientists, who typically operate in parallel non-contiguous environments. They receive different training, pursue different career paths, work in different departments in academic settings, and are housed in different buildings.

Opportunities for cross-fertilization have been engineered out of both the research and training environments, and visions for new and unique career trajectories are often dimmed by the lack of flexibility, tolerance, and resources/incentives for scientists seeking to solve real world problems.

The training need as we see it is not just about getting more people interested in pursuing the traditional career paths of physician scientists, but rather about preparing scientists to do the work needed to move the results of basic discovery through the early stages of development.

As Dr. Garret FitzGerald, Director of the Institute for Translational Medicine and Therapeutics at the University of Pennsylvania, has written, "...to realize this potential in the form of actual therapeutics, we need investigators with a sophisticated understanding of the principles of human medicine and expertise in both basic and human pharmacology, who are capable of projecting their preclinical work across the translational divide. Such expertise in translational medicine and therapeutics has become scant in academia, industry, and the regulatory bodies."^{iv}

Dr. FitzGerald recommends a number of different actions needed to build this human capital, beginning with rebranding the field to make it more appealing to young scientists, establishing desirable career structures and rewards for them, and of course providing funding mechanisms for their training. The NIH's CTSA program, with its natural focus on training, is the perfect locus for this and it is a strategic goal of the consortium; some academic institutions have begun establishing programs in translational science on their own as well, as they perceive it to be good preparation for a career in either academic research or industry.

Rebranding, funding, and modeling career paths and incentives for translational researchers should be a federal funding priority.

Question #16: What are the highest impact opportunities for public/private partnerships related to the bioeconomy? What shared goals would these partnerships pursue, which stakeholders might participate, and what mutually reinforcing commitments might they make to support the partnership?

Our response to this question and the one that follows on pre-competitive collaboration are closely linked, as they are intimately related topics, so most of what we say in this section can be considered to apply to the next one as well.

We highlight a number of new models of R&D collaboration, particularly early-stage, and highlight lessons learned from them in our recent report [Trends in Translation](#), which also seeks to identify broader applications of these existing models and opportunities for new collaboration mechanisms.

The high costs and high risk of medical research make effective public/private partnerships increasingly critical. While research and development have always been multi-sectoral efforts, in this era of complex science and constrained resources no one can afford to duplicate efforts, fail to learn from failures, or drop the ball on a promising compound for lack of funding or other resources.

Before the Administration prioritizes high-impact opportunities for public/private partnerships (or pre-competitive collaborations), however, we strongly believe it must consider whether it is creating an **environment** that is conducive to these activities and whether there are legal and regulatory barriers to creating a culture in which it is acceptable for the parties to work together – a cooperative system rather than an adversarial one. Here are a few areas to examine.

Conflict-of-interest (COI). Translational research can only thrive if crosstalk between basic scientists and developers is not only allowed but also encouraged. Yet in many respects we are moving backwards in this regard, with policies becoming more restrictive and applying more broadly. While public trust in the scientific process and the results of research is essential, translating the results of publicly funded research more efficiently and effectively into improved

human health is nearly impossible without building relationships and collaborations among all the entities and sectors that fund and conduct medical research. These relationships do not always represent a “conflict” of interest; they frequently represent a “convergence” of interest.

We have often heard in interviews with scientists inside and outside NIH that the agency’s current ethics policy governing individual conflicts of interest has had at times a stifling effect on recruitment and retention of clinical investigators. In the view of some, it has prevented or impeded important collaborations in translational and clinical research. While there is a genuine need for clear ethics guidelines, the current policies have the potential to inhibit NIH’s ability to serve national needs, by hindering collaboration between the public and private sector that is critical to bringing research findings to development.

NIH’s survey of its staff in the immediate aftermath of the 2005 policy change for its own employees showed that most believed the rules were too restrictive and that they would negatively impact NIH’s ability to complete its mission, along with recruitment and retention, and that NIH should have just enforced existing rules better rather than strengthening the rules.

The Administration must consider the impact of its current and any future conflict-of-interest regulations on its ability to foster effective public/private partnership.

Technology transfer. We applaud the Obama Administration’s focus on accelerating the process of transferring technology from government-funded laboratories to the private sector; much can be done to make access to technology and research materials from within the NIH and from NIH-funded research at universities more transparent and user-friendly. Some of that work is already underway, with efforts such as **CTSA-IP** – a Web site that aggregates and markets technologies from academic institutions that are part of NIH’s Clinical and Translational Research Awards (CTSA) network as well as NIH itself, with the goal of enhancing research activity and private partnerships across the CTSA consortium – and the Kauffman Foundation’s **iBridge Network**.

But measuring success solely by the number of licenses or amount of royalty revenue generated would be a mistake. Pushing more discoveries out the door faster will not ensure more treatments to help patients (or even more jobs, if the technologies and the companies fail); this is why NIH’s focus on helping move discoveries farther down the path towards proof-of-concept is so important. Consideration must be given to the metrics used to evaluate the technology transfer activities of government agencies and of academic technology transfer offices; as we all know, “you get what you measure.” We need to be thinking less about patents than about productivity. Universities need to create incentives for their faculty to collaborate appropriately with industry and commercialize their discoveries; they need to change their internal metrics of success. Are there “surrogate markers” such as amount of follow-on investment leveraged, or the stage of research at which a technology is licensed, that can be brought into the equation?

Opportunity: Drug repurposing.

One area ripe for significant federal involvement in creating public/private partnerships is drug repurposing. It used to be that finding new uses for existing drugs or abandoned compounds occurred primarily through serendipity, but now the process for identifying potential “hits” is becoming more deliberate, less expensive, and faster. Strategic collaborations between the public, private, and nonprofit sectors are springing up to shepherd research efforts around abandoned compounds that might work in other diseases, and ensure the policies, processes, and resources are in place to permit their appropriate reuse.

This is an area of keen interest for Francis Collins and the NIH because the proposed NCATS could play an instrumental role, given the private sector’s lack of clear incentives to do so. NIH is already pursuing such efforts through initiatives such as **The Learning Collaborative**, an effort of its Therapeutics for Rare and Neglected Diseases (TRND) program that utilizes the

infrastructure of the National Chemical Genomics Center; in a pilot project, TRND signed a cooperative research and development agreement (CRADA) with the Leukemia and Lymphoma Society and the University of Kansas Medical Center to develop an approved drug for arthritis, Auranofin, as a potential clinical therapy for a rare blood cancer. NIH is seeking an industry partner to develop the product for this use, if the project is successful.

Opportunity: Clinical trial design innovation.

A number of important and successful public/private partnerships have been developed by the nonprofit **Foundation for the NIH** that almost certainly would not exist without this trusted third-party intermediary playing the critical convening and management role. The most recent example is the highly anticipated I-SPY 2 clinical trial combining personalized medicine with a novel trial design to develop potentially life- saving new breast cancer drugs. It was carefully crafted to allow the activity of drugs to be assessed much earlier in the research process, potentially enabling drugs to be developed and approved using fewer patients, less time, and fewer resources, potentially shaving years and hundreds of millions of dollars off the process. The treatment phase of this trial will test multiple investigational drugs that are thought to target the biology of each participant's tumor. This effort brings together a number of major pharmaceutical companies with intellectual property interests to protect, a consortium of 20 academic research institutions conducting the trials, and importantly the FDA, which will need to accept the results of the trial for product approval.

The Administration should continue to target areas such as clinical trial design innovation and drug repurposing as priorities for public/private partnership.

Question #17: What are the highest impact opportunities for pre-competitive collaboration in the life sciences, and what role should the government play in developing them? What can be learned from existing models for pre-competitive collaboration both inside and outside the life-sciences sector? What are the barriers to such collaborations and how might they be removed or overcome?

Over the last years there has been increasing interest within the biotech and pharmaceutical industries in collaborating more across companies and sectors on pre-competitive areas of research. Even though the concept remains ill-defined - with questions about where "pre-competitive" ends and "competitive" begins, how intellectual property should be treated, and whether it is possible to create a "marketplace" that will help facilitate the exchange of pre-competitive information – such efforts are cropping up across the landscape, some initiated by government, some by patient-driven foundations, some among companies interested in supporting tools and technologies beneficial to the industry as a whole.

Interestingly, the **oil and gas industry** – a similarly capital-intensive, high-risk industry with long timeframes for R&D – has realized the importance of pre-competitive collaboration, and now almost all exploration and development is executed through or supported by consortia of competing companies and service providers, who pool data and expertise in an effort to manage downside risk; companies take a more holistic view, and understand the need for sharing data to reduce risk and price volatility. Similarly, the pharmaceutical industry needs more data-sharing and trusted third parties to help it tackle common challenges.

One such trusted third-party is the **Foundation for the NIH** (mentioned above in reference to the I-SPY 2 trial). One of its most prominent initiatives is the **Biomarkers Consortium**, created to develop and qualify promising biomarkers critical to the development of new therapies for the prevention, early detection, diagnosis, and treatment of disease. Founding members include NIH, FDA, Centers for Medicare and Medicaid Services (CMS), and the pharmaceutical and biotechnology industry trade associations; other partners include 28 for-profit companies and 35 nonprofit organizations. Despite their importance, research into biomarkers is expensive and

high-risk and often not taken on by academic or industry researchers; it benefits all and directly profits none. The Consortium has invested significant amounts of human and financial capital in building the intellectual property, data-sharing, and anti-trust frameworks necessary to make the collaboration among disparate stakeholders work. One high-profile initiative of the Consortium has been the pathbreaking **Alzheimer's Disease Neuroimaging Initiative**, which is contributing to a flood of scientific papers and studies of new drugs to slow or stop Alzheimer's.

Among the most important factors considered key to the success of the Biomarkers Consortium has been the involvement of FDA. Their advice and engagement on the qualification of biomarkers being studied is a "crucial incentive for sustaining the interest and engagement of pharmaceutical companies."

Biomarkers is clearly an area crying out for more pre-competitive collaboration. The **Parkinson's Progression Markers Initiative** is another example of a significant effort, in this case initiated and intermediated by a patient-driven research foundation, the Michael J. Fox Foundation for Parkinson's Research.

There are also a number of pre-competitive collaborations oriented around data generation and aggregation. **Sage Bionetworks** is a nonprofit organization founded by former industry scientists that has explicitly aims "to establish a pre-competitive position for human disease biology" – that is, to fundamentally shift the business model of disease research away from building and patenting unique disease models, and redefining what are considered "commercial assets." Its first initiative, the Sage Commons, is an information platform for integrating mega-datasets from industry, academic, and government contributors, and making them available to be used in integrative genomics analysis and building predictive computational disease models.

Another initiative by Sage, in conjunction with the Genetic Alliance and a number of pharma companies, is called the Clinical Trial Comparator Arm Partnership, which will specifically compile datasets from the non-proprietary comparator or placebo arm of clinical trials (which are not commercially sensitive intellectual property) and establish an open repository of datasets and derived disease models for use by academic and commercial researchers. A third effort, called Arch2POCM (Archipelago to Proof of Concept in Medicine), will take a step forward from these efforts to demonstrate the feasibility of a highly efficient precompetitive drug discovery effort driven by the sharing and availability of data. No intellectual property will be generated through the POCM stage.

Another significant pre-competitive collaboration is the **Structural Genomics Consortium**, a not-for-profit organization formed to determine the three dimensional structures of proteins of medical relevance, and place them in the Protein Data Bank without restriction. Based at the Universities of Toronto and Oxford and the Karolinska Institutet in Stockholm, its current funders include GSK, Eli Lilly, Pfizer, the Novartis Research Foundation, the Wellcome Trust, and Canadian granting agencies. While it has an open access policy and puts all its findings in the public domain, it is driven by the needs of drug discovery and the development of new therapies for cancer, diabetes, obesity, and psychiatric disorders.

Some of the factors for success of pre-competitive collaborations that we have observed include:

- Trusted third parties to create and manage initiatives;
- Data-sharing;
- Learning from other collaborations' data-sharing, intellectual property and anti-trust frameworks;
- A focus on the ultimate needs of therapy discovery and development - i.e. "pre-competitive" does not mean "non-competitive" or that everything is free and open;
- Engagement with FDA.

Summary of Recommendations

We at *FasterCures* encourage the Administration to look for big ideas that seek to address not only the scientific challenges of our times, but the process challenges that keep science from benefiting patients – and ultimately our economy and global competitiveness. These may not be headline-worthy efforts, but we firmly believe they are what will prove transformational.

In sum, here are our recommendations:

- Look for opportunities to support cross-sector, cross-disciplinary collaboration in all initiatives supported by the Bioeconomy Initiative, and to involve patient groups and venture philanthropies in priority-setting and implementation.
- Prioritize Grand Challenges that address the challenges of linking large datasets and biospecimens in an intelligent way that addresses privacy concerns.
- Develop an initiative with pilot projects that would create medical research IT modules which could be attached (plug and play) or retrofitted to existing health data systems that were built without the capacity to accommodate research.
- Consider the need to harmonize standards for collecting genomic and molecular data and integrating these into an EHR.
- Support translational science programs and initiatives at NIH.
- Prioritize support for regulatory science initiatives at FDA and build stronger, mutually beneficial links to NIH for this purpose.
- Rebrand, fund, and model career paths and incentives for translational researchers.
- Make the R&D tax credit permanent and increase it by 25%.
- Promote cutting-edge areas like nanotechnology, personalized medicine, and stem cell research through funding and regulatory support.
- Review federal policies in areas such as conflict-of-interest and technology transfer to ensure they support cross-sector collaboration.
- Create and engage in pre-competitive and public/private partnerships in critical areas such as biomarker research and qualification and drug repurposing.

You have raised many critical issues in this Request for Information, and we applaud you for it. These are big problems, not given to easy solutions. As is often the case in human endeavors, the most significant challenges are often not the scientific or technological ones but the behavioral and cultural ones.

We are happy to discuss these issues with you at greater length any time. Thank you again for the opportunity to respond to this important set of questions.

Sincerely,

Margaret Anderson
Executive Director
FasterCures
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FasterCures is a nonprofit, nonpartisan center of the Milken Institute dedicated to improving the medical research system so that we can speed up the time it takes to get important new medicines from discovery to patients. Through our programmatic activities, we work with many patient advocacy, venture philanthropy, and medical research organizations across the disease spectrum to improve the effectiveness and efficiency of the medical research enterprise, and transform the way we pursue, fund, and conduct medical research. Learn more about our [programs](#).

ⁱ Pharmaceutical Research and Manufacturers of America (PhRMA). 2008. *Profile 2008*. Washington, DC: PhRMA

ⁱⁱ Martino, M. (2011, October 25) Collins: NIH targeting bottlenecks in drug development process. *FiercePharma*.

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